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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,279	09/03/2003	Patricia Marie Momin		4465

7590

12/15/2004

GLAXOSMITHKLINE

Corporate Intellectual Property - UW2220

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/654,279	Applicant(s) MOMIN ET AL.	
	Examiner Mark Navarro	Art Unit 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-23 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/663,289.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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### **DETAILED ACTION**

Applicants preliminary amendment filed September 3, 2003 has been received and entered. Claims 1-13 have been cancelled and new claims 14-23 have been added. Consequently claims 14-23 are pending in the instant application.

#### ***Specification***

1. The disclosure is objected to because of the following informalities: Applicants continuing data statement recites a claim of priority to multiple applications. The status of each of these applications should be recited as a US Patent or abandoned.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

2. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treatment with immunogenic compositions, does not reasonably provide enablement for methods of treatment with vaccine compositions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed towards methods of treating a mammal susceptible to a viral, bacterial or parasitic infection by administering an effective vaccine, wherein the vaccine is for numerous etiological agents (e.g., HSV type I, HSV type II, CMV, etc.).

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However, this claim refers to multiple vaccines for which the scientific community does not yet recognize the existence of one.

Wang et al (World Journal of Gastroenterology Vol. 10, No. 15, pp 2157-2162, August 1, 2004) reports that "there are no commercial vaccines for hepatitis E available in the world." See abstract.

Hilleman (PNAS USA, Vol. 101 Suppl 2, pp 14560-6, October 5, 2004) reports that protective vaccines against hepatitis C are highly unlikely, short of a major breakthrough. (See abstract).

Tramont et al (Expert Opinion of Emerging Drugs Vol. 8, No. 1, pp 37-45, May 2003) set forth that the development of an effective HIV vaccine remains an elusive goal. (See abstract).

Given the lack of guidance in the specification, the lack of working examples, and the unpredictable nature of the invention as demonstrated by Wang et al, Hilleman and Tramont et al, one of skill in the art would be forced into excessive experimentation to practice the instantly claimed invention.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 14-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,146,632. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims encompasses methods of treating a mammal comprising administering an antigen and/or antigenic composition with an adjuvant comprising a metabolizable oil and alpha tocopherol in the form of an oil in water emulsion.

4. Claims 14-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,623,739. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims encompasses vaccines for treatment comprising an antigen and/or antigenic composition with an adjuvant comprising a metabolizable oil and alpha tocopherol in the form of an oil in water emulsion.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro  
Primary Examiner  
December 7, 2004